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IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF ARIZONA

Annette Rodriguez and Roberto
Rodriguez,

Plaintiffs,

v.

Howmedica Osteonics Corp., a New
Jersey Corporation, d/b/a Stryker
Orthopaedics,

Defendant.

NO.

COMPLAINT

Plaintiffs, Annette Rodriguez and Roberto Rodriguez, by and through undersigned counsel, and for their claims against the Defendant, allege as follows:

1. This is an action for damages relating to Defendant's development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective device sold under the name "The Rejuvenate System" (hereinafter "Rejuvenate" or "defective device").

PARTIES

2. Plaintiffs, Annette Rodriguez and Roberto Rodriguez, husband and wife, reside in Surprise, Arizona.



- 1 3. Defendant, Howmedica Osteonics Corporation, d/b/a Stryker Orthopaedics, is
2 a corporation organized and existing under the laws of New Jersey and
3 conducts business throughout the United States, including the State of
4 Arizona. Its principal place of business is 325 Corporate Drive, Mahwah, New
5 Jersey 07430.
6

7 **JURISDICTION AND VENUE**

- 8
9 4. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The
10 amount in controversy exceeds \$75,000 exclusive of interests and costs, and
11 this is an action by an individual Plaintiff against a Defendant with its principal
12 place of business in another state.
13
14 5. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a)(2)
15 because a substantial part of the events or omissions giving rise to the claim
16 occurred in this judicial district, including but not limited to: the marketing of
17 the defective device; the surgical implantation of the defective device; and the
18 surgical revision of the defective device.
19

20 **FACTUAL ALLEGATIONS**

- 21 6. Defendant designed, manufactured, marketed, and warranted the Stryker
22 Rejuvenate device and placed its defective device into the stream of interstate
23 commerce.
24
25 7. The Stryker Rejuvenate device consists of a femoral stem, modular neck,
26 femoral ball, and acetabular cup. It has a metal-on-metal junction (a Morse
27 Taper Junction) where the modular neck connects both to the femoral stem
28 and the femoral ball.



- 1 8. Defendant's defective design utilizes Chromium and Cobalt metals along with
2 a TMZF alloy (composed of titanium, iron, molybdenum, and zirconium).
- 3 9. Defendant marketed the Rejuvenate device by specifically addressing
4 concerns of patients and doctors related to metal-on-metal junctions.
5 Defendant stated "the modular junction construct is designed to maintain
6 strength and durability. The Rejuvenate System combines the material
7 characteristics of TMZF and Cobalt Chrome for the stem and neck implants
8 respectively. Laboratory testing demonstrates the compatibility of these
9 materials **without concern for fretting and corrosion.**"
- 10 10. Despite Defendant's assurance, the defective design and manufacture of the
11 Stryker Rejuvenate device allows fretting and corrosion at the metal-on-metal
12 junctions; specifically, at the femoral stem and modular neck and at the
13 modular neck and femoral ball.
- 14 11. The result of the fretting and corrosion is the release of metal ions, including
15 Chromium and Cobalt, into the tissue surrounding the hip joint. Chromium
16 and Cobalt ions destroy the surrounding tissue and bone often causing
17 psuedotumors and metallosis. The fretting and corrosion and subsequent
18 release of ions manifests in elevated levels of Chromium and Cobalt which
19 can be detected in the blood stream of the patient.
- 20 12. Defendant knew that hip implants utilizing Chromium and Cobalt alloys posed
21 significant health risks based on the widely reported problems with other
22 similarly designed hip implants. Even with this knowledge, Defendant
23 continued to manufacture and distribute the defectively designed Stryker
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1 Rejuvenate device in reckless disregard for safety of patients such as Plaintiff,
2 Annette Rodriguez.

3
4 13. Due to the defective design, manufacturing, and marketing of the Stryker
5 Rejuvenate device and the resulting high incidence of fretting and corrosion at
6 the metal-on-metal junctions, Defendant recalled the Stryker Rejuvenate
7 device in July 2012.

8
9 14. A defectively designed and manufactured Stryker Rejuvenate device left the
10 hands of Defendant in its defective condition. Defendant delivered the
11 defective device into the stream of commerce and allowed it to be implanted
12 in the right hip of Plaintiff, Annette Rodriguez, on November 4, 2011, at
13 Banner Boswell Medical Center, 10401 West Thunderbird Blvd., Sun City,
14 Arizona 85351 by Dr. Joseph Janzer.

15
16 15. As a direct and proximate result of Defendant placing the defective device into
17 the stream of commerce, Plaintiff, Annette Rodriguez, required a painful hip
18 revision surgery of her right hip performed on March 6, 2013 at Banner
19 Baywood Medical Center, 6644 East Baywood Avenue, Mesa, Arizona 85206
20 by Dr. Earl Feng.

21
22 16. Plaintiff's postoperative diagnosis included "failed right total hip arthroplasty
23 with a recalled femoral component and metallosis."

24
25 17. Plaintiff's doctor noted the preoperative workup indicated no infection but
26 Plaintiff did have "significantly elevated cobalt and chromium levels in her
27 blood." Dr. Feng indicated Plaintiff was symptomatic and she had a recalled
28 modular prosthesis with metallosis. During the procedure, Plaintiff's doctor



1 removed a large pseudotumor from the hip joint. Dr. Feng “removed huge
2 pieces of soft tissue, which had built up over time from a reaction from the
3 meatalosis [sic]” and there was “fretting at the taper of the neck” of the Stryker
4 hip implant device.
5

6 18. The release of Chromium and Cobalt from fretting and corrosion at the metal-
7 on-metal junction in the defectively design and subsequently recalled Stryker
8 Rejuvenate device proximately caused Plaintiff, Annette Rodriguez’ injuries.
9 These injuries include:
10

- 11 a. damage to her bodily tissues surrounding the defective device;
- 12 b. elevated blood serum levels of Chromium and Cobalt; and
- 13 c. a painful, expensive, and physically risky hip revision surgery.
14

15 19. Furthermore, as a direct and proximate result of Defendant placing the
16 defective device into the stream of commerce, Plaintiff, Annette Rodriguez,
17 has suffered and continues to suffer both injuries and damages, including but
18 not limited to: past, present and future physical and mental pain and
19 suffering; past, present and future medical, hospital, rehabilitative and
20 pharmaceutical expenses; and other related damages. Plaintiff Roberto
21 Rodriguez has been injured and damaged in the loss of consortium and
22 service of his wife, Annette Rodriguez.
23
24

25 **THE STRYKER REJUVENATE HISTORY**

26 20. At all times material hereto, Defendant developed, tested, assembled,
27 manufactured, packaged, labeled, prepared, distributed, marketed, supplied,
28 and sold the defective device under the name “The Rejuvenate System”



1 either directly or indirectly, to members of the general public throughout the
2 United States, including to Plaintiff, Annette Rodriguez.

3
4 21. On June 3, 2008, Defendant received clearance from the United States Food
5 and Drug Administration (hereinafter "FDA") to sell its Rejuvenate device in
6 the United States.

7
8 22. In February 2009, Stryker released its Rejuvenate Modular Primary Hip
9 System, the latest evolution in the Company's OmniFit and Secure-Fit Hip
10 systems, which was approved for market by the FDA on June 3, 2008. The
11 Rejuvenate Modular hip is an extension of the Stryker Modular Hip, which
12 was approved for market by the FDA on September 13, 2007.

13
14 23. The Rejuvenate device is a modular hip replacement prosthesis. It is
15 indicated for patients requiring primary total hip arthroplasty or replacement
16 due to painful disabling joint disease of the hip resulting from non-
17 inflammatory degenerative arthritis.

18
19 24. Unlike most prosthetic hip implants, the Rejuvenate device is an artificial hip
20 replacement device consisting of two basic components: a chrome cobalt
21 modular neck that is inserted into a titanium femoral stem. The Rejuvenate
22 device can be used with any number of bearing surface components
23 comprised of the ball or artificial femoral head and an acetabular cup or
24 socket.

25
26 25. The titanium stem is manufactured utilizing a proprietary titanium alloy
27 consisting of titanium, molybdenum, zinc, and iron. This alloy was designed
28 and patented by Defendant and is unlike any titanium alloy utilized in the



1 manufacture of other prosthetic hip implants. The Defendant claims in its
2 promotional materials for the Rejuvenate device that its alloy is both stronger
3 and less rigid than other titanium alloys. It also claims that the particular
4 titanium alloy has been tested and proven to resist fretting and corrosion.
5

6 26. According to Defendant's materials, the Rejuvenate device was developed to
7 optimize anatomic restoration by providing options that offer enhanced
8 stability, proven modularity, and intra-operative flexibility. With a wide range of
9 femoral stem and neck combinations and an extensive range of length,
10 version and offset, the Rejuvenate Modular Primary Hip System was
11 marketed to enable surgeons to better personalize the implant to a patient's
12 unique anatomy.
13

14 27. The Rejuvenate device is comprised of separate femoral stem and neck
15 components and offers a variety of sizing options intra-operatively. The
16 benefit, according to Stryker, was that by allowing the surgeon to
17 independently manage leg length, neck version, and femoral offset, the
18 Rejuvenate provides surgeons the ability to better personalize the
19 biomechanics of a patient's hip replacement.
20

21 28. The Rejuvenate device combines the material characteristics of TMZF (Ti-
22 12Mo-6Zr-2Fe) with a plasma sprayed coating of commercially pure Ti and
23 PureFix HA for the stem and CoCr for the neck. Defendant claims that
24 laboratory testing demonstrates the compatibility of these materials without
25 concern for fretting and corrosion.
26
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1 29. Despite Defendant's claims, this material combination has been reported to
2 cause corrosion. Since the 1980's, medical and scientific literature has
3 reported corrosion to be a problem when Ti and CoCr have been used at
4 modular junctions. In its marketing and sale of the device, Stryker represented
5 and warranted that its proprietary materials alleviate this problem.
6

7 30. On July 6, 2012, the FDA posted notice that Defendant initiated a voluntary
8 recall of the Rejuvenate and ABG II modular neck stems.
9

10 **URGENT SAFETY NOTICES AND RECALLS**

11 31. In April, 2012, Defendant issued an Urgent Field Safety Notice to surgeons
12 and hospitals in the United States.

13 32. In this notice, Defendant acknowledged that it had received reports of device
14 failure due to heavy metal contamination. The Notice specifically referred to
15 failures at the taper neck junction between the neck and stem due to fretting
16 and corrosion.
17

18 33. This fretting and corrosion was exactly the same failure mechanism that
19 Defendant had warranted would not occur because of the Rejuvenate's
20 design and composition. It was also exactly the same failure mechanism that
21 the medical and scientific community had been studying and documenting in
22 modular device design since the 1980's.
23

24 34. The Notice went on to describe symptoms and findings identical to those
25 experienced by Plaintiff.
26

27 35. Among those specifically mentioned in the Notice were tissue necrosis,
28 metallosis, adverse soft tissue reaction, and pseudotumor formation.



1 36. Almost immediately following the Notice, Defendant issued a voluntary recall
2 of the Stryker Rejuvenate and ABGII in Canada. In the recall notice,
3 Defendant stated that it was amending the Instructions for Use for the device
4 to include warnings that Defendant was on notice of the issues described in
5 the Notice above.
6

7 37. Finally, on July 6, 2012, Defendant issued a voluntary recall of all Stryker
8 Rejuvenate and ABG II stems. As part of the recall notice, Defendant once
9 again cited reports of device failure due to heavy metal fretting and corrosion.
10

11 **THE FEDERAL REQUIREMENTS**

12 38. Federal regulation states, "Recall means a firm's removal or correction of a
13 marketed product that the Food and Drug Administration considers to be in
14 violation of the laws it administers and against which the agency would initiate
15 legal action, e.g. seizure." See 21 CFR § 7.3(g).
16

17 39. Federal regulation states: "Recall classification means the numerical
18 designation, i.e., I, II or III, assigned by the Food and Drug Administration to a
19 particular product recall to indicate the relative degree of health hazard
20 presented by the product being recalled." See 21 CFR § 7.3(m).
21

22 40. Federal regulation states: "Class II is a situation in which use of, or exposure
23 to, a violative product may cause temporary or medically reversible adverse
24 health consequences or where the probability of serious adverse health
25 consequences is remote." See 21 CFR § 7.3(m).
26

27 41. The classification of the product withdrawals and corrections of the
28



1 confirms by definition, that the devices were in violation of federal law and that
2 initiation of legal action or seizure would be indicated for these devices.

3
4 42. Pursuant to federal law, a device is deemed to be adulterated if, among other
5 things, it fails to meet established performance standards, or if the methods,
6 facilities, or controls used for its manufacture, packing, storage, or installation
7 are not in conformity with federal requirements. See 21 U.S.C. § 351.

8
9 43. Pursuant to federal law, a device is deemed to be misbranded if, among other
10 things, its labeling is false or misleading in any particular manner, or if it is
11 dangerous to health when used in the manner prescribed, recommended, or
12 suggested in the labeling thereof. See 21 U.S.C. § 352.

13
14 44. Pursuant to federal law, manufacturers are required to comply with FDA
15 regulation of medical devices, including FDA requirements for records and
16 reports, in order to prohibit introduction of medical devices that are
17 adulterated or misbranded, and to assure the safety and effectiveness of
18 medical devices. In particular, manufacturers must keep records and make
19 reports of any medical device that may have caused or contributed to death or
20 serious injury, or if the device has malfunctioned in a manner likely to cause
21 or contribute to death or serious injury. Federal law also mandates that the
22 FDA establish regulations requiring a manufacturer of a medical device to
23 report promptly to the FDA any correction or removal of a device undertaken
24 to reduce a risk to health posed by the device, or to remedy a violation of
25 federal law by which a device may present a risk to health. See 21 U.S.C. §
26
27
28 360(i).



1 45. Pursuant to FDA regulation, adverse events associated with a medical device
2 must be reported to the FDA within 30 days after the manufacturer becomes
3 aware that a device may have caused or contributed to death or serious
4 injury, or that a device has malfunctioned and would be likely to cause or
5 contribute to death or serious injury if the malfunction was to recur. Such
6 reports must contain all information reasonably known to the manufacturer,
7 including any information that can be obtained by analysis, testing, or other
8 evaluation of the device, and any information in the manufacturer's
9 possession. In addition, manufacturers are responsible for conducting an
10 investigation of each adverse event and must evaluate the cause of the
11 adverse event. See 21 CFR § 803.50.

12 46. Pursuant to federal regulation, manufacturers of medical devices must also
13 describe in every individual adverse event report whether remedial action was
14 taken in regard to the adverse event, and whether the remedial action was
15 reported to the FDA as a removal or correction of the device. See 21 CFR §
16 803.52.

17 47. Pursuant to federal regulation, manufacturers must report to the FDA in five
18 business days after becoming aware of any reportable MDR event or events,
19 including a trend analysis that necessitates remedial action to prevent an
20 unreasonable risk of substantial harm to the public health. See 21 CFR §
21 803.53.

22 48. Pursuant to federal regulation, device manufacturers must report promptly to
23 the FDA any device corrections and removals, and maintain records of device
24



1 corrections and removals. FDA regulations require submission of a written
2 report within ten working days of any correction or removal of a device
3 initiated by the manufacturer to reduce a risk to health posed by the device, or
4 to remedy a violation of the Act caused by the device, which may present a
5 risk to health. The written submission must contain, among other things, a
6 description of the event giving rise to the information reported and the
7 corrective or removal actions taken, and any illness or injuries that have
8 occurred with use of the device, including reference to any device report
9 numbers. Manufacturers must also indicate the total number of devices
10 manufactured or distributed which are subject to the correction or removal
11 and provide a copy of all communications regarding the correction or removal.
12
13 See 21 CFR § 806.

- 14
15
16 49. Pursuant to federal regulation, manufacturers must comply with specific
17 quality system requirements promulgated by the FDA. These regulations
18 require manufacturers to meet design control requirements, including but not
19 limited to conducting design validation to ensure that devices conform to
20 defined user needs and intended uses. Manufacturers must also meet quality
21 standards in manufacturing and production. Manufacturers must establish and
22 maintain procedures for implementing corrective actions and preventive
23 actions. They must investigate the cause of nonconforming products and take
24 corrective action to prevent recurrence. Manufacturers are also required to
25 review and evaluate all complaints and determine whether an investigation is
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27
28



necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR § 820.

50. Pursuant to federal regulation, a manufacturer must report to the FDA any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device. Federal regulations require that: "A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification."

51. Specifically, it is believed that with respect to the Rejuvenate device, Defendant failed to timely report adverse events; failed to timely conduct failure investigations and analysis; failed to timely report any and all information concerning product failures and corrections; failed to timely and fully inform the FDA of unanticipated adverse effects, increases in the incidence of adverse effects, or device failures necessitating a labeling, manufacturing or device modification; failed to conduct necessary design validation; and sold a misbranded and adulterated product.

COUNT ONE
STRICT PRODUCTS LIABILITY
DEFECTIVE MANUFACTURE

52. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–51.

53. At all times material hereto, the Defendant was the manufacturer, designer, distributor, seller, and/or supplier of the Stryker Rejuvenate hip implant device.



- 1 54. The Stryker Rejuvenate device manufactured, sold, distributed, supplied,
2 and/or placed in the stream of commerce by the Defendant was defective in
3 its manufacture and construction when it left the hands of the Defendant
4 because it deviated from product specifications and/or applicable federal
5 requirements for medical devices and posed a serious risk of injury and/or
6 death.
7
- 8 55. Defendant knew or reasonably should have known that the Stryker
9 Rejuvenate hip implant device, as manufactured or constructed, was
10 defective and posed an unreasonable risk of harm to individuals, including the
11 Plaintiff, who used the Stryker Rejuvenate hip implant device as intended by
12 Defendant.
13
- 14 56. As a direct and proximate result of the defective manufacture or construction
15 of the Defendant's Stryker Rejuvenate device and Plaintiff's use of the
16 defective Stryker Rejuvenate device as designed, manufactured, sold,
17 supplied, and introduced into the stream of commerce by Defendant and/or
18 the Defendant's failure to comply with federal requirements, Plaintiff suffered
19 serious physical injury, harm, damages, and economic loss and will continue
20 to suffer such harm, damages, and economic loss in the future.
21
- 22 57. Plaintiffs contend that the conduct of the Defendant is attended by
23 circumstances of fraud, malice, or willful and wanton conduct, and constitutes
24 a flagrant disregard for human life which warrants the imposition of exemplary
25 damages.
26
27
28



COUNT TWO
STRICT PRODUCTS LIABILITY
DESIGN DEFECT

58. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–57.

59. The Stryker Rejuvenate device as manufactured and supplied by Defendant was defective in design and formulation in that, when it left the hands of the Defendant, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, it was more dangerous than an ordinary customer would expect, and/or failed to comply with federal requirements for these medical devices.

60. The foreseeable risks associated with the design or formulation of the Stryker Rejuvenate device includes, but is not limited to, the fact that the design or formulation of the Stryker Rejuvenate device is more dangerous than a reasonably prudent consumer would expect when used in its intended manner and/or it failed to comply with federal requirements. The defective design permits fretting and corrosion at the Morse Taper Junctions as discussed above. This defective design causes the very condition Defendant marketed and warranted it would not cause.

61. As a direct and proximate result of the defective design of the Defendant's Stryker Rejuvenate device and Plaintiff's use of the defective Stryker Rejuvenate device as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendant and/or the Defendant's failure to comply with federal requirements, Plaintiff suffered serious physical injury,



1 harm, damages, and economic loss and will continue to suffer such harm,
2 damages, and economic loss in the future.

3 62. Plaintiffs contend that the conduct of the Defendant is attended by
4 circumstances of fraud, malice, or willful and wanton conduct, and constitutes
5 a flagrant disregard for human life which warrants the imposition of exemplary
6 damages.
7

8
9 **COUNT THREE**
10 **STRICT PRODUCTS LIABILITY**
11 **FAILURE TO WARN**

12 63. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–62.

13 64. At all times material hereto, the Defendant was the manufacturer, designer,
14 distributor, seller, and/or supplier of the Stryker Rejuvenate hip implant device
15 and sold the Stryker Rejuvenate device to patients knowing they would then
16 be implanted in patients who were in need of a hip prosthesis.

17 65. The Stryker Rejuvenate device was expected to, and did, reach the Plaintiff
18 without substantial change or adjustment in its condition as designed,
19 manufactured, and sold by the Defendant.
20

21 66. The Stryker Rejuvenate device as designed, developed, tested,
22 manufactured, marketed, sold, and/or placed in the stream of commerce by
23 Defendant was in a dangerous and defective condition when it left the hands
24 of the Defendant and posed a threat to any user of the device.
25

26 67. Plaintiff was and is in the class of persons that Defendant actually considered,
27 or should have considered, to be subject to the harm caused by the defective
28 nature of the Stryker Rejuvenate device.



- 1 68. The Stryker Rejuvenate device was implanted and used in the manner for
2 which it was intended. Plaintiff's use of the Stryker Rejuvenate device as
3 intended by Defendant resulted in severe physical, emotional, financial, and
4 other injuries to the Plaintiff.
5
- 6 69. Defendant knew or should have known that the Stryker Rejuvenate device as
7 designed, developed, tested, manufactured, marketed, sold, and/or placed in
8 the stream of commerce by Defendant was in a dangerous and defective
9 condition when it left the hands of the Defendant and posed a threat to any
10 user of the device.
11
- 12 70. Defendant failed to provide adequate and timely warnings or instructions
13 regarding the Stryker Rejuvenate device and its known defects.
14
- 15 71. As a direct and proximate result of the Defendant's failure to warn Plaintiff of
16 the dangerous condition of the Stryker Rejuvenate device and Plaintiff's use
17 of the defective Stryker Rejuvenate device as designed, manufactured, sold,
18 supplied, and introduced into the stream of commerce by Defendant and/or
19 the Defendant's failure to comply with federal requirements, Plaintiff suffered
20 permanent physical injury, harm, damages, and economic loss and will
21 continue to suffer such harm, damages, and economic loss in the future.
22
- 23 72. Plaintiffs contend that the conduct of the Defendant is attended by
24 circumstances of fraud, malice, or willful and wanton conduct, and constitutes
25 a flagrant disregard for human life which warrants the imposition of exemplary
26 damages.
27
28



COUNT FOUR
NEGLIGENCE

73. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–72.

74. Defendant had a duty to exercise reasonable care in the design, manufacture, sale, and/or distribution of the Stryker Rejuvenate devices into the stream of commerce, including a duty to assure that its products did not pose a significantly increased risk of bodily harm and adverse events as well as a duty to comply with federal requirements.

75. Defendant had a duty to follow the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the Stryker Rejuvenate devices, and otherwise distributing the Stryker Rejuvenate devices.

76. Defendant negligently designed, manufactured, tested, assembled, labeled, supplied, marketed, sold, advertised, and warned against, the Stryker Rejuvenate devices as set forth above.

77. Defendant's acts and omissions constitute an adulteration, misbranding, or both, as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a) and 333(a)(2), and constitute a breach of duty, subjecting Defendant to civil liability for all damages arising therefrom.

78. Plaintiff, as a purchaser of Stryker Rejuvenate device, is within the class of persons that the statutes and regulations previously described herein are



1 designed to protect, and Plaintiff's injuries are the type of harm these statutes
2 and regulations are designed to prevent.

3
4 79. Defendant failed to exercise ordinary care and/or was negligent and/or
5 wanton in the design, formulation, manufacture, sale, testing, quality
6 assurance, quality control, labeling, marketing, promotion, and distribution of
7 the Stryker Rejuvenate devices into interstate commerce because Defendant
8 knew or should have known that these products caused significant bodily
9 harm and were not safe for use by consumers, and/or through their failure to
10 comply with federal requirements.

11
12 80. Despite the fact that Defendant knew or should have known that the Stryker
13 Rejuvenate devices posed a serious risk of bodily harm to consumers,
14 Defendant continued to manufacture and market the Stryker Rejuvenate
15 devices for use by consumers and/or continued to fail to comply with federal
16 requirements.

17
18 81. Defendant knew or should have known that consumers, such as Plaintiff,
19 would foreseeably suffer injury as a result of Defendant's failure to exercise
20 ordinary care as described above, including the failure to comply with federal
21 requirements.

22
23 82. As a direct and proximate result of Defendant's negligence and/or
24 wantonness, Plaintiff suffered serious physical injury, harm, damages and
25 economic loss and will continue to suffer such harm, damages, and economic
26 loss in the future.
27
28



1 83. Plaintiffs contend that the conduct of the Defendant as described above,
2 including, but not limited to, its failure to adequately design and manufacture,
3 as well as its continued marketing and distribution of the Stryker Rejuvenate
4 devices when Defendant knew or should have known of the serious health
5 risks these devices created and/or the failure to comply with federal
6 requirements, is attended by circumstances of oppression, fraud, malice,
7 willfulness, wantonness, and constitutes a conscious, reckless, and flagrant
8 disregard for human life, which warrants the imposition of exemplary
9 damages.
10
11

12 **COUNT FIVE**
13 **BREACH OF EXPRESS WARRANTY**

14 84. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–83.

15 85. Defendant expressly warranted that the Stryker Rejuvenate device was a safe
16 and effective orthopedic device for patients requiring a hip replacement.

17 86. Defendant expressly warranted that the Stryker Rejuvenate device would not
18 cause fretting and corrosion of the metals in the hip system.
19

20 87. The Stryker Rejuvenate device manufactured and sold by Defendant did not
21 conform to these express representations because they caused serious injury
22 to Plaintiff when used as recommended and directed.
23

24 88. As a direct and proximate result of Defendant's breach of warranty, Plaintiff
25 has suffered serious physical injury, harm, damages, and economic loss and
26 will continue to suffer such harm, damages, and economic loss in the future.
27
28



COUNT SIX
VIOLATION OF ARIZONA CONSUMER FRAUD ACT
A.R.S. § 44-1521 et seq.

89. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–88.

90. Plaintiff, Annette Rodriguez is a person within the meaning of the Arizona Consumer Fraud Act (“the Act”).

91. Defendant is a person within the meaning of the Act for all purposes herein.

92. The false, deceptive, and misleading statements and representations made by Defendant alleged above are unlawful practices within the meaning of the Act.

93. Defendant engaged in the unlawful practices alleged above and those unlawful practices occurred or were committed in the course, vocation, or occupation of Defendant’s medical device business.

94. The unlawful practices engaged in by the Defendant as alleged above significantly impact the public as actual or potential customers.

95. As a direct and proximate result of the Defendant’s unlawful practices committed in violation of the Act, Plaintiff, Annette Rodriguez suffered injuries, damages, and losses as alleged herein.

96. Plaintiff is entitled to all damages permitted by the A.R.S. § 44-1528 and A.R.S. § 44-1534 of this Act, including actual damages sustained, civil penalties, attorneys’ fees, and costs of this action. Also, the State of Arizona is entitled to statutory penalties from Defendant for each violation of the Act pursuant to A.R.S. § 44-1531.



COUNT SEVEN
LOSS OF CONSORTIUM

97. Plaintiffs incorporate herein by reference the allegations in paragraphs 1–96.

98. Plaintiff Roberto Rodriguez is, and at all times relevant was, the lawful husband of Annette Rodriguez.

99. As a direct, legal, and proximate result of the culpability and fault of the Defendant, be such fault through strict liability or negligence, Plaintiff Roberto Rodriguez suffered the loss of support, service, love, companionship, affection, society, intimate relations, and other elements of consortium, all to his general damage in an amount in excess of the jurisdictional minimum of this court.

100. Plaintiffs demand judgment against the Defendant for compensatory and punitive damages such as a jury may award, and such other relief as the Court deems just and proper in order to remedy the Plaintiff's loss of consortium. Plaintiff demands such other and further relief as this Honorable Court deems proper and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request judgment be entered against Defendant Howmedica Osteonic Corporation as follows:

1. For an award of compensatory damages in excess of Seventy-Five Thousand Dollars (\$75,000.00);
2. For an award of punitive or exemplary damages against Defendant;
3. For reasonable attorney fees and costs;



1 4. For pre-judgment interest; and

2 5. For such further and other relief this Court deems just and equitable.

3 **JURY DEMAND**

4
5 Plaintiffs demand a trial by jury on all issues so triable with the maximum
6 number of jurors permitted by law.

7
8 RESPECTFULLY SUBMITTED this 18th day of April 2013.

9
10 **O'STEEN & HARRISON, PLC**

11 

12 _____
13 Jonathan V. O'Steen
14 300 W. Clarendon Ave., Suite 400
15 Phoenix, Arizona 85013-3424
16 Attorneys for Plaintiffs

17 I hereby certify that on the 18th day of April 2013, I electronically transmitted the
18 attached document to the Clerk's Office using the CM/ECF System for filing.

19 /s/ Jonathan V. O'Steen

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